

JAN 16 2003

K023682

Summary of Safety Information**NOVARE SURGICAL SYSTEMS, INC.****Premarket Notification, Section 510(k)****JANUARY 15, 2003****Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92**Device Name:** ENclose™ Anastomosis Assist Device**Common Name(s):** Vascular Clamp**Classification Name(s):** Vascular Clamp**Manufacturer:****Name:** Novare Surgical Systems, Inc.**Number:** 2954739**Address:** 10231 Bubb Road
Cupertino, CA 95014**Classification(s):**

Sec. 870.4450 Vascular clamp. (a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily. (b) Classification. Class II (performance standards).

Device Class: Class II for the requested indications**Classification Panel:** Cardiovascular Devices Panel**Product Code(s):** DXC**Equivalent Predicate Device:**

The ENclose™ Anastomosis Assist Device is substantially equivalent to the following legally marketed vascular clamp:

1. InCluder™ Vascular Clamp - Novare Surgical Systems, Inc., K010694

Sec. 870.4450 Vascular clamp. (a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily. (b) Classification. Class II (performance standards).

Device Class: Class II**Product Code(s):** DXC

The new anastomosis device is identical to the previous device. Equivalency can be seen with respect to place of manufacture, physical appearance, functional testing, material certification, surgical technique and indications for use. A feature comparison chart follows this section.

FEATURE	ENclose™ Anastomosis Assist Device	InCluder™ Vascular Clamp -K010694	SE?
Indications for Use:	The ENclose™ Anastomosis Assist Device is intended for use by cardiac surgeons in place of partial occluding clamps during coronary artery bypass grafting (CABG) procedures requiring one to three proximal anastomoses in ascending aortas free of atheromatous disease.	Identical, except single anastomosis	YES
Materials:	Medical grade plastic, stainless steel and silicone	Identical	YES
Design:	Clamp	Identical	YES
Sterilization:	Radiation (e-beam)	Identical	YES
Manufacturer:	Novare Surgical Systems, Inc.	Identical	YES
Product Code:	DXC	Identical	YES
K - Number:	K023682	K010694	YES

Device Description:

The change is limited to a request for multiple use. The modified ENclose™ Anastomosis Assist Device is a intra-operative device used to assist in the creation of one or more proximal anastomosis sites in the execution of coronary artery bypass grafting (CABG).

Clinical Testing Summary. Clinical testing conducted in Canada and Europe demonstrate the functional equivalence of the added ENclose™ Anastomosis Assist Device. The one to three vessel use ENCLOSE™ Anastomosis Assist Devices' level of performance is substantially equivalent to the performance of the existing legally marketed ENCLOSE™ Anastomosis Assist Device (InCluder™, K010694) cleared for single vessel use. The collected clinical data demonstrate that one to three proximal anastomoses are no more difficult and are just as safe as the existing single anastomosis procedure performed using the previously cleared ENCLOSE™ Anastomosis Assist Device.

Please refer to the product instructions for use for a more complete listing of indications, contra-indications, warnings, cautions and precautions.

Company Contact:

Mr. Kerry Pope
Novare Surgical Systems, Inc.
10231 Bubba Road
Cupertino, CA 95014
408.873.3161

Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

Special Controls:

Special controls were published by FDA. The following special controls are believed to apply to the marketing of class II devices:

- (i) Compliance with material standards,
- (ii) Compliance with biocompatibility standard, and Compliance with specified labeling requirements.

Novare Surgical Systems, Inc. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

Sterility Processing:

The ENclose™ Anastomosis Assist Device is provided sterile and is designed strictly for single patient use. The device may not be cleaned, reprocessed or reused under any circumstances. The product must be handled, stored and placed into use in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following accepted surgical sterile technique.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2003

Novare Surgical Systems, Inc.
c/o Mr. David Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

Re: K023682

EncloseTM Anastomosis Assist Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: October 31, 2002
Received: November 1, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

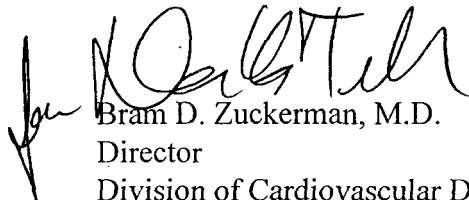
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023682

Device Name(s): ENclose™ Anastomosis Assist Device

Indication(s) for Use:

The ENclose™ Anastomosis Assist Device is intended for use by cardiac surgeons in place of partial occluding clamps during coronary artery bypass grafting (CABG) procedures requiring one to three anastomoses in ascending aortas free of atheromatous disease.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023682

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐
(Optional format 1-2-96)